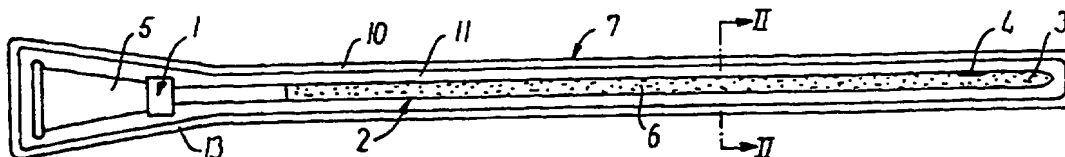


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 25/00		A1	(11) International Publication Number: WO 98/19729 (43) International Publication Date: 14 May 1998 (14.05.98)
(21) International Application Number: PCT/DK97/00395 (22) International Filing Date: 18 September 1997 (18.09.97) (30) Priority Data: 1224/96 1 November 1996 (01.11.96) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebæk (DK). (72) Inventors; and (75) Inventors/Applicants (for US only): NØSTED, Ulrik [DK/DK]; Agnetevej 2,2, DK-2800 Lyngby (DK). TORSTENSEN, Jan [DK/DK]; Egeløvsvej 30, DK-2830 Virum (DK). KAYERØD, Helle [DK/DK]; Stefansgade 56, DK-2200 Copenhagen N (DK). TANGHØJ, Allan [DK/DK]; Jellerød Have 59, DK-2980 Kokkedal (DK). (74) Agent: RAFFNSØE, Knud, Rosenstand; Internationalt Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taastrup (DK).			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: **A URINARY CATHETER ASSEMBLY WITH A READY-TO-USE CATHETER**

(57) Abstract

A urinary catheter assembly comprises a urinary catheter (1) having on at least a part of its surface a hydrophilic surface layer (6) intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7) having a cavity (11) for accommodation of the catheter (1). The package (7) is made with walls of a gas impermeable material to accommodate a catheter pretreated with said liquid swelling medium for long time preservation of said low-friction surface character and provision of a ready-to-use catheter assembly.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

A Urinary Catheter Assembly with a Ready-to-Use Catheter.

This invention relates to a Urinary catheter assembly comprising a urinary catheter having on at least a part of its surface a hydrophilic surface layer intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package having a cavity for accommodation of the catheter.

10 Urinary catheters of the kind to which the invention pertains are known, inter alia, from EP-A-0 217 771, EP-A-0 586 324 and WO 94/16747, whereas various forms of catheter packages are known from US-A-3,035,691, US-A- 3,648,704, US-A-3,967,728, US-A-15 4,204,527, US-A-4,379,506, US-A-5,226,530, US-A-5,454,798, GB-A-2,284,764, EP-A-0 677 299 and DK Design Registration No. 0932 1986.

US-A-3,648,704, US-A-3,967,728, GB-A-2,284,764 and EP-A-0 677 299 discloses a conventional urinary
20 catheter assembly comprising a catheter of the kind where prior to insertion of the catheter into the urethra the tip of the catheter is to be lubricated with a gel-like lubricant and a package where such a lubricant is accommodated in a rupturable pouch connected or located within the package itself adjacent to
25 the tip of the catheter or is supplied together with the catheter package for connection therewith prior to use of the catheter.

US-A-5,226,530 discloses a prelubricated catheter
30 and package assembly, in which a urinary catheter prelu-bricated with a conventional lubricant is accommodated in a package comprising a first receptacle for stowing the catheter and inside said receptacle a secondary receptacle for receiving the projecting or
35 distal end of the catheter to the tip of which the

lubricant is applied. The two receptacles are wrapped in an outside enclosing receptacle the contents of which can be sterilized in a suitable manner.

The use of a sequence of three receptacles which
5 must all be opened before use of the catheter makes the operation unduly difficult for disabled users, such as tetraplegics or sclerosis patients.

An important feature of any urinary catheter used for intermittent catheterisation of the bladder of
10 an incontinent user is the ability of the catheter to slide easily through the urethra without exposing the urethral walls to any risk of damage. Catheters of the kind to which the invention pertains have been developed to meet this need by imparting an extremely low
15 friction character to at least the part of the surface of the catheter which is actually introduced into the urethra. The low friction surface character is obtained by incorporating into the relevant part of the catheter at least a hydrophilic surface layer, typically in the
20 form of a coating, and exposing this layer or coating to contact with a liquid swelling medium immediately prior to use.

In order to maintain the low friction surface character during location of the catheter in the
25 urethra and subsequent withdrawal therefrom and hereby reduce stinging pain it is further known to incorporate an osmolality promoting agent, such as NaCl, in the hydrophilic coating.

When catheters of this kind are used directly by
30 end users outside the medical environment of a hospital or a clinic, e.g. by tetraplegic patients who often have a very poor dexterity, and therefore need a very simple insertion procedure, the most common liquid swelling medium used for preparation of the catheter
35 immediately prior to use would be normal tap water.

In order to reduce the risk of infection inherent with the performance of intermittent catheterisation of the bladder both the actual swelling medium used and the environment in which the catheterisation is performed need, however, to be as clean and antiseptic as possible. Evidently, this need may be very difficult to meet in many daily life situations, as where catheterisation must be performed outside the user's normal daily environment, e.g. in public toilets, where neither the water supply nor the general state of cleanliness can be expected to be of a sufficiently high standard. Moreover, many disabled users have severe difficulties in entering available toilet rooms due to simple physical barriers like narrow access ways, stairs and the like.

On this background, it is the object of the invention to improve and facilitate the performance of intermittent urinary catheterisation in any type of environment by providing a ready to use urinary catheter assembly comprising a catheter which can be withdrawn from its package and is prepared for direct insertion in the urethra and in a substantially sterile condition, whereby the general quality of life for users of intermittent catheterisation would be greatly improved.

In order to meet this and other objects of the invention, as set forth in the following, a urinary catheter according to the invention is characterised in that the package is made with walls of a gas impermeable material for accommodation of a catheter pretreated with said liquid swelling medium for long time preservation of said low-friction surface character and provision of a ready-to-use catheter assembly.

The term "gas impermeable" material should be understood in this context to mean any material that will be sufficiently tight against diffusion by evapor-

ation of the actual liquid swelling medium for a period exceeding the recommended shelf life time of the catheter assembly which could be up to five years, typically 36 months.

5 Thereby, preparation of the catheter with the liquid swelling medium prior to use is avoided, so that the catheter is ready for insertion into the urethra immediately upon withdrawal for the package which can be designed for easy opening and withdrawal of the
10 catheter.

Thus, the joint between the two sheets of film material of the package may advantageously be a welded joint which may be formed to allow easy opening of the package for withdrawal of the prepared catheter.

15 Such a welded joint may comprise a part provided as a peelable joint permitting separation of said sheets from each other for withdrawal of said catheter from the package.

In order to reduce the amount of liquid swelling
20 medium required for activation of the hydrophilic surface coating of the catheter, the latter may advantageously be provided with means preventing said swelling medium from getting into contact with internal or external surface parts of the catheter not provided
25 with said hydrophilic layer for an activation period during which said medium is applied to the surface part provided with said hydrophilic layer.

In the following, the invention will be explained in more detail by means of an embodiment illustrated in
30 the accompanying drawings, in which

figures 1 and 2 are an upper plan view and a cross-sectional view, respectively, of an embodiment of a urinary catheter assembly according to the invention;

figure 3 illustrates opening of a catheter package
35 as shown in figures 1 and 2;

figure 4 illustrates a part of a catheter provided with means to reduce the amount of liquid swelling medium required for activation of a hydrophilic surface coating; and

5 figure 5 illustrates a further embodiment.

In the embodiment shown in figs. 1 and 2 the urinary catheter assembly of the invention is intended for intermittent catheterisation of the bladder of a user and comprises a urinary catheter 1 having a catheter
10 tube 2 with cross-sectional and longitudinal dimensions suitable for introduction of the catheter through the urethra.

The catheter tube 2 extends from a distal inlet end 3, in which urine inlet openings 4 are provided,
15 towards a proximal end, at which the catheter tube is connected with an outlet member 5 designed for connection of the catheter with a hose member (not shown) for transport of urine withdrawn from the bladder to a urine collection bag (not shown).

20 On a substantial part of its length from the distal end the catheter tube is, in the illustrated embodiment, coated on its external surface with a hydrophilic surface coating 6 of a kind known per se, which by preparation with a liquid swelling medium
25 prior to use of the catheter provides an extreme low friction character of the catheter surface to enable the catheter to slide very easily through the urethra without exposing the urethral walls to any risk of damage. A hydrophilic surface layer may, however, be
30 provided by other means and may include a catheter tube of which the active part to be located in the urethra is made entirely of a hydrophilic material.

The catheter 1 is accommodated in its entirety in a package 7 formed by two sheets 8 and 9 of a gas-
35 impermeable thermoplastic film material such as a

multiple layer film material comprising e.g. aluminium, welded together along a welding seam 10 which constitutes a joint defining a cavity 11 narrowly surrounding the catheter tube 2 and a widened end section 12 5 joining the cavity 11 through a transitional section 13 matching the external dimensions of the outlet or connector member 5.

According to the invention, the hydrophilic surface coating 6 of the catheter 1 is prepared to 10 activate its low friction character prior to arrangement of the catheter 1 in package 7 or immediately following said arrangement before closing the package by treatment with a liquid swelling medium. Since the welding seam 10 is arranged to provide a narrow cavity 15 11 around the catheter tube 2 the amount of swelling liquid needed for preparation of the hydrophilic coating 6 can be kept low. Experiments have verified that by suitable design of the cavity the amount of swelling liquid may be reduced to a volume of 2 to 50 20 ml, preferably 2 to 15 ml for female and 5 to 30 ml for male catheters.

To facilitate withdrawal of the prepared catheter 1 from the package 7 the welding joint may, as illustrated in figure 3, comprise a part 10a adjacent the 25 distal end of the catheter tube providing a peel-off joint permitting easy separation of plastic film sheets 8 and 9. Thereby, the package 7 itself will serve as an applicator to be gripped by the user to permit introduction of the catheter tube without contamination.

30 Due to the gas-impermeability of the package 7 the swelling medium may be introduced in the package during the assembling operation prior to completion of the welding and will thereby immediately prepare the hydrophilic coating. The package will itself prevent the 35 coating from drying out and preserve the low friction

character of the surface coating to keep the catheter in a ready to use condition at all times. This would have the inherent advantage that no further preparation step is required prior to use, so that the operation 5 will be reduced to opening of the package 7 for immediate withdrawal of the catheter without the delay resulting from the required preparation period.

Due to the desirability of limiting the amount of swelling liquid, the catheter may be provided with 10 means preventing the swelling liquid from getting into contact with internal or external surface parts of the catheter 1 not provided with the hydrophilic coating 6, during the period needed for preparation of the hydrophilic coating to activate its low friction character. 15 Such means may in a simple manner comprise the application of a film layer 55 of a material soluble by the actual swelling medium to said internal or external surface parts.

As shown in figure 4 this may be done in the most 20 simple way by application of such film layers 55 over the catheter inlet openings 4. Thereby, substantially the entire quantity of swelling medium will be effectively used for the preparation of the hydrophilic surface coating.

25 In figure 5 a further embodiment is illustrated in which the catheter package 51 is formed integrally with a urine collecting bag 52. For disabled users like tetraplegics who as described in the foregoing may have severe difficulties in entering available toilet rooms 30 such an integration of the urine collecting bag with the catheter package is a significant practical advantage making the use of the catheter totally independant of the availability of a toilet room. The catheter 1 is located in a relatively narrow tapering part 53 joining 35 the collection bag 52. In this case the catheter 1 will

in use not be completely removed from package 51. Instead the distal end of the tapering part 53 may be opened by peel-off separation of two plastic film sheets from which the package 51 is composed. Thereby,
5 the catheter 1 may be introduced by an operation as described above for the embodiment in figure 3.

A catheter assembly according to the invention may well comprise a number of catheters packed in individual packages with sufficient gas impermeable properties
10 to last a certain short period, said individual packages being arranged in a common package providing the prescribed long term gas impermeability.

P A T E N T C L A I M S

1. A urinary catheter assembly comprising at least one urinary catheter (1) having on at least a part of
5 its surface a hydrophilic surface layer (6) intended to produce a low-friction surface character of the catheter by treatment with a liquid swelling medium prior to use of the catheter and a catheter package (7) having a cavity (11) for accommodation of the catheter (1),
10 c h a r a c t e r i z e d in that the package (7) is made with walls of a gas impermeable material for accommodation of a catheter pretreated with said liquid swelling medium for long time preservation of said low-friction surface character and provision of a ready-to-
15 use catheter assembly.

2. A urinary catheter assembly as claimed in claim 1, c h a r a c t e r i z e d in that the catheter package (7) is formed from two sheets (8, 9) of gas impermeable film material connected with each other by
20 a gas impermeable joint (10) defining the cavity (11) for accommodating the catheter (1).

3. A urinary catheter assembly as claimed in claim 2, c h a r a c t e r i z e d in that the catheter package (7) is of a general elongate shape with said
25 joint (10) arranged to define said cavity (11) to accommodate the catheter (1) in a substantially linear orientation.

4. A urinary catheter assembly as claimed in claims 2 or 3, c h a r a c t e r i z e d in that said
30 joint (10) is arranged to provide said cavity (11) with a cross-section narrowly surrounding the catheter (1).

5. A urinary catheter assembly as claimed in any of claims 2 to 4, c h a r a c t e r i z e d in that said joint (10) is a welding joint.

35 6. A urinary catheter assembly as claimed in claim

10

5, c h a r a c t e r i z e d in that said welding joint (10) comprises a part (10a) at the end of the package remote from said compartment (12) providing a peel-off joint to separate said sheets (8, 9) from each other for withdrawal of said catheter (1) from the package (7).

7. A urinary catheter assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that the catheter (1) is provided with means preventing said swelling medium from getting into contact with internal or external surface parts of the catheter not provided with said hydrophilic coating (6) for an activation period during which said medium is applied to the surface part provided with said hydrophilic coating (6).

8. A urinary catheter assembly as claimed in claim 7, c h a r a c t e r i z e d in that said means comprises a film layer (55) of a material soluble by said swelling medium applied to said parts not provided with said hydrophilic coating.

9. A urinary catheter assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that said package includes a bag (52) communicating with the catheter (1) for collection of urine.

25 10. A urinary catheter assembly as claimed in any of the preceding claims, c h a r a c t e r i z e d in that said liquid swelling medium is selected from the group comprising an aqueous solution, an isotonic aqueous solution, an isotonic aqueous solution of sodium chloride and sterile water.

1/2

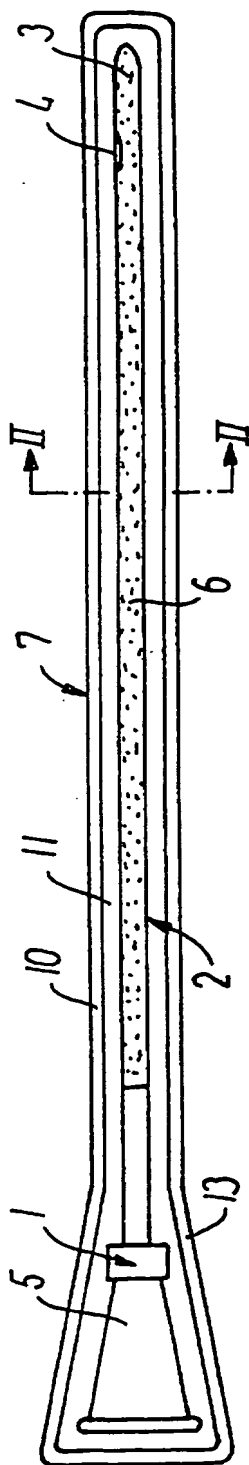


FIG. 1



FIG. 2

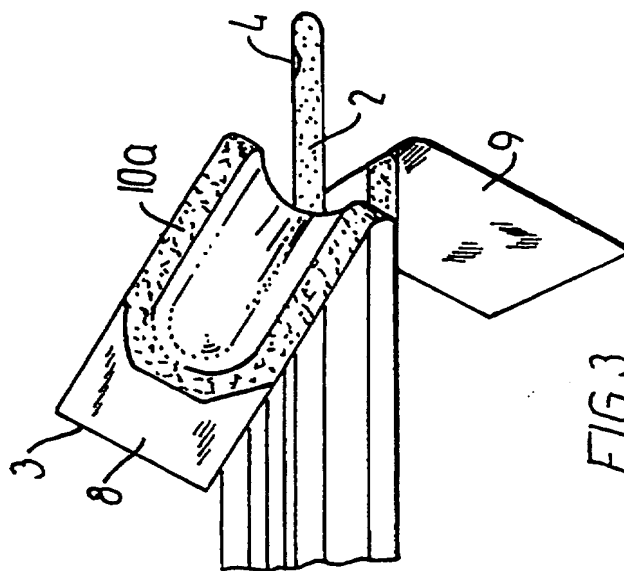


FIG. 3

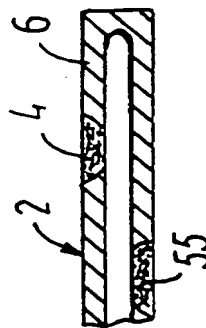


FIG. 4

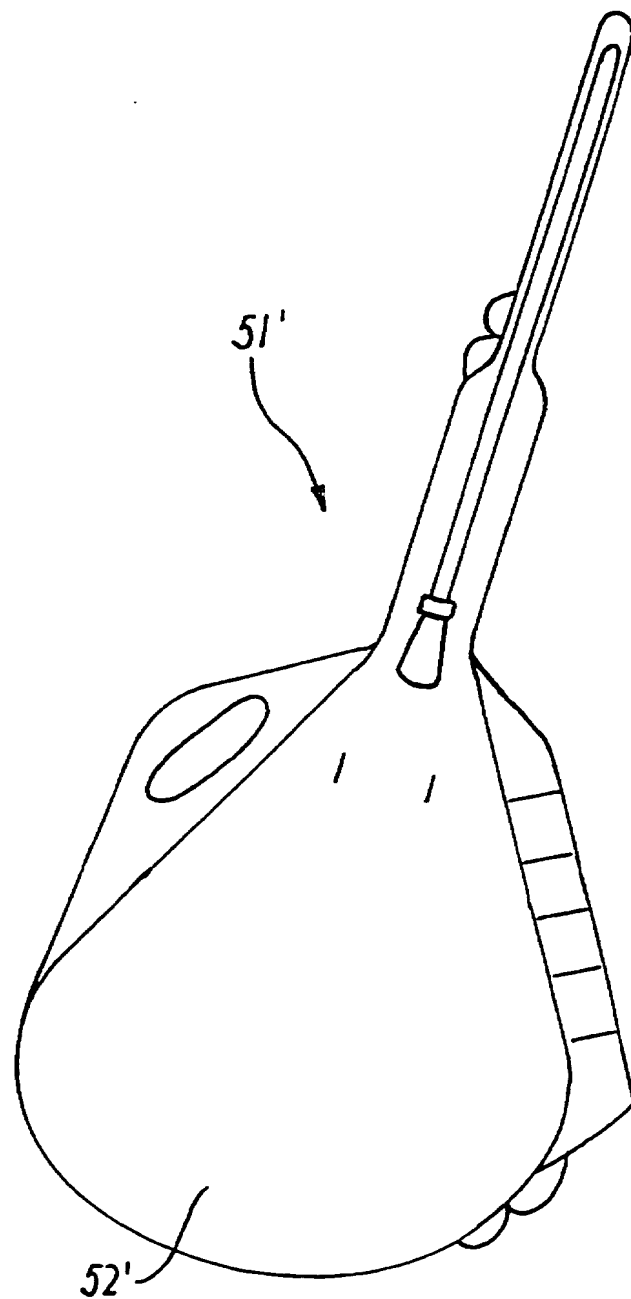


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No. --

PCT/DK 97/00395

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61M 25/00 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
WPI, CAPLUS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 9630277 A1 (COLOPLAST A/S), 3 October 1996 (03.10.96), page 3, line 8 - line 9; page 6, line 6 - line 8; page 8, line 30 - line 35, claim 5	1-10
Y	US 3967728 A (ROBERT L. GORDON ET AL), 6 July 1976 (06.07.76), column 2, line 43 - line 64; column 3, line 20 - line 35, figures 1,4-6, claims	1-10
A	WO 9416747 A1 (COLOPLAST A/S), 4 August 1994 (04.08.94)	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
22 January 1998		29 -01- 1998
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Sofia Nikolopoulou Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No. --
PCT/DK 97/00395

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5226530 A (JOHN H. GOLDEN), 13 July 1993 (13.07.93), column 2, line 50 - line 56; column 3, line 3 - line 28, abstract -----	1

INTERNATIONAL SEARCH REPORT
Information on patent family members

07/01/98

International application No. ---
PCT/DK 97/00395

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
WO	9630277	A1	03/10/96	AU	5270496 A	16/10/96
				EP	0815037 A	07/01/98
				NO	974417 A	19/11/97
US	3967728	A	06/07/76	GB	1465544 A	23/02/77
WO	9416747	A1	04/08/94	AU	660873 B	06/07/95
				AU	5880694 A	15/08/94
				DK	7193 A,B	22/07/94
				EP	0639990 A	01/03/95
US	5226530	A	13/07/93	NONE		